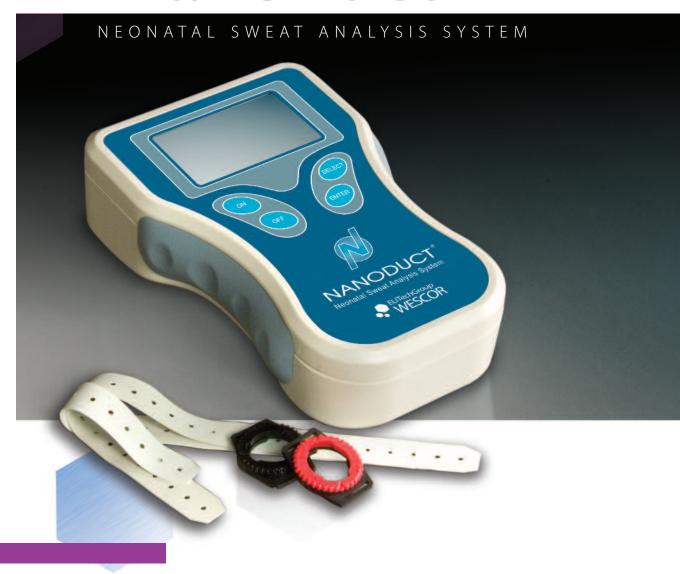


Nanoduct®



Laboratory CF Diagnosis in the first days of life



NANODUCT NEONATAL SWEAT ANALYSIS SYSTEM

Initial Sweating Rate Displayed Automatically

As soon as sweat enters the microconductivity cell, the display alerts the operator. After a very short interval, the display reads out the initial sweating rate and gives continuous readings of real-time conductivity.

Requires Only 3 Microliters of Sweat!

The miniscule conductivity sensor allows a reading at only 3 microliters of sweat, which, for reasonably mature glands usually happens within 6 minutes after applying the sensor.

Shorter Stimulation Time

Improved Pilogel lontophoretic
Discs yield maximal gland stimulation after 2.5 minutes of iontophoresis at 0.5 mA total current, which is desirable both in safety and time of involvement for neonates.

Neonate-to-Adult Capability

While the Nanoduct is designed for neonates, it works equally well on patients of any age.

Automatic Averaging of Conductivity

waits 3 minutes after the first display of conductivity, then commences a 5-minute averaging period, and displays the resultant average value as the reportable diagnostic result.

Compact Hand-Held Unit

NANODUCT

Nanoduct's trim, hand-held case simplifies handling, set-up, and operation.

Lab Report Software

The addition of a USB port allow a Windows-formatted computer interface providing printed test results—a valuable feature of the

REFERENCES

- Farrell PM, Kosorok MR, Laxova A, et al. Nutritional benefits of neonatal screening for cystic fibrosis. N Engl J Med 1997: 337; 963-969.
- Farrell PM, Kosorok MR, Rock MJ, et al. Early diagnosis
 of cystic fibrosis through neonatal screening prevents severe malnutrition and improves long term
 growth. Pediatrics 2001: 107; 1-13.
- Webster HL, Quirante CG. Micro-flowcell conductometric sweat analysis for cystic fibrosis diagnosis. Ann Clin Biochem, 2000: 37; 399-407.
- 4. Hammond KB, Turcios NL, Gibson LE. Clinical evaluation of the Macroduct Sweat Collection System and

- conductivity analyzer in the diagnosis of cystic fibrosis. J Pediatr 1994: 124; 255-260.
- Webster HL, Sweat conductivity is a valid analysis for cystic fibrosis. Proceedings of the international conference on neonatal screening for cystic fibrosis. Caen, France 1998: 101-104.
- Heeley ME, Woolf DA, Heeley AF. Indirect measurements of sweat electrolyte concentration in the laboratory diagnosis of cystic fibrosis. Arch Dis Child 2000: 82; 420-424.
- Webster HL, A critical appraisal of cystic fibrosis sweat-testing guidelines. Amer Clin Lab 2001: 20 (3); 39-47.
- Barben J, Ammann RA, Metlagel A, Schoeni MH, and on behalf of the Swiss Pediatric Respiratory Research Group. Conductivity determined by new sweat analyzer compared with chloride concentrations for the diagnosis of cystic fibrosis. J Pediatr 2005:146;183-188.
- Desax M-C, Ammann RA, Hammer J, Schoeni MH, Barben J. Nanoduct sweat testing for rapid diagnosis in newborns, infants and chidren with cystic fibrosis. Eur J Pediatr 2008: 167; 299-304.

It is vital to perform this test as soon as possible after birth. With Nanoduct it becomes extremely simple and reliable.

Nanoduct[®]

Early diagnosis and treatment can significantly improve both the quality of life and the lifespan of children born with cystic fibrosis. ^{1,2} The proven diagnostic effectiveness of analyzing electrolyte concentration in sweat makes it vital to perform this test as soon as possible after birth.

ELITechGroup has long been the leading innovator in the laboratory diagnosis of cystic fibrosis with the Macroduct® Sweat Collector and its companion, the Sweat-Chek™ Sweat Conductivity Analyzer.

GROUND BREAKING INNOVATION BASED ON PROVEN TECHNOLOGY

The Nanoduct Neonatal Sweat Analysis System combines and miniaturizes the proven collection and analysis technologies of Macroduct and Sweat-Chek to accommodate the tiny limbs of newborn infants, and provides reliable laboratory diagnosis of CF as soon as a newborn's sweat glands are capable of producing sweat.

Innovative features of the Nanoduct System include the special electrode/sensor holders that are positioned on the patient's limb before iontophoresis. The holders make electrode

placement simple and secure. They also guarantee that the sensor collecting surface is perfectly registered with the stimulated skin area and attachment pressure is optimal when the sensor is attached.

Nanoduct incorporates the classic method of inducing sweat by pilocarpine iontophoresis. The pilocarpine is carried into the dermis of the patient from improved Pilogel® Iontophoretic Discs by a controlled DC electric current supplied by the Nanoduct System.

This is followed by continuousflow analysis of sweat electrolyte concentration using the unique conductivity sensor. Electrodes and the sensor are connected to the Nanoduct System via a single control cable.

The Nanoduct Neonatal Sweat Analysis System simplifies the sweat test and for the first time makes possible reliable laboratory diagnosis of CF in the first days of life.

CONTINUOUS-FLOW ANALYSIS OF ELECTROLYTE CONTENT

When the sensor is attached to the patient, the stimulated sweat emerging from the sweat glands is anaerobically directed into a microconductivity cell within the sensor. This provides a continuous display of the electrical conductivity in the freshly emerged sweat. Conductivity has been shown to be the equal of chloride in its ability to discriminate diagnostically between CF and non-CF subjects. 3,4,5,6,7,8,9

SEPARATE COLLECTION PHASE IS ELIMINATED

Continuous-flow analysis while the sensor is on the limb, eliminates potential handling errors, saves laboratory time, and ensures accuracy by providing virtually infinite replications of the analysis on freshly excreted sweat. A further benefit: any inadvertent contamination of the sensor collecting surface will be dissipated before the final reading is displayed.

IMPROVED PILOGEL® DISCS

- Increased pilocarpine concentration
- Iontophoresis time reduced to only 2.5 minutes
- Buffered to prevent pH changes

Specifications

Nanoduct® Neonatal Sweat Analysis System Model 1030

Readout	128 \times 64 LCD graphic display (non-backlit). Supports up to 8 lines of 18 characters or numerals, with multi-lingual support (English, French, German, and Spanish).
Sound	Alert and Alarm signals
Keyboard	ON, OFF, SELECT and ENTER keys
Electrode Connection	6-pin locking medical connector to mate with induction/conductivity cell cable
Serial Outputs	RS-232 (ASCII format) 9-pin D-sub male connector USB – device Type B receptacle
Electrical	Four AA Alkaline batteries (NEDA 15A, IEC LR6) Typical solid-state, over-current circuit protection 3.0 VDC lithium coin cell for the real-time clock
Sweat Induction Control	Current profile controlled for use with Pilogel Iontophoretic Discs with multiple fail-safe circuits to limit current. Nominal current is 0.5 (\pm 0.02) mA for 2.5 minutes (\pm 0.2 Sec.). Maximum fail-safe current limited to 5 mA.
Real-Time Clock	± 2 minutes per year (battery backed)
Operating Temperature	15 to 30 °C (59 to 86 °F)
Storage Temperature	0 to 60 °C (32 to 140 °F)
Instrument (H x W x D)	7.5 x 5 x 2 in (19.1 x 12.7 x 5.1 cm)
Weight	1.2 lb (0.5 kg)
Carrying Case	13.5 x 10.5 x 4 in (34.3 x 26.7 x 10.2 cm)
Sweat Analysis Conductivity Readout	mmol/L (equivalent NaCl)
Conductivity Range	3 to 200 mmol/L
Precision	CV ≤ 1% from 25 to 150 mmol/L (equivalent NaCl)
Initial Sweat Rate	0 to 50 g/m²/min
Calibration	Single-point automatic calibration at 80 mmol/L (equivalent NaCl) using the AC-081 Calibration Plate.

ALSO AVAILABLE:

Macroduct® Sweat Collection System Sweat-Chek™ Sweat Analyzer



© ELITechGroup inc 2014 PRINTED **USA** 60-0021-01B

NANO.MAY14 - 20

Please contact your sales representative for product availability in your country.

WORLDWIDE OFFICES

 Headquarters
 T: +33 1 41 45 07 13

 Australia
 T: +61 1800 815 098

 Benelux
 T: +31 313 430 574

 Brazil
 T: +55 27 3025 1415

 France
 T: +33 4 83 36 10 82

 Italy
 T: +39 02 48 40 35 42

 Middle East & Africa
 T: +971 4 375 2744

 New Zealand
 T: +64

 Serbia
 T: +381

 Switzerland
 T: +41

 The Netherlands
 T: +31

 UK
 T: +44

 United States
 T: +1 4

T: +64 800 555 611 T: +381 11 2467119 T: +41 26 663 86 60 T: +31 313 430574 T: +44 1442 869320 T: +1 435 752 6011

